



MAY 16 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Laurie Jordan
Regulatory Affairs Specialist
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K050938

Trade/Device Name: Knee Fusion Nail
Regulation Number: 21 CFR 888.3030
Regulation Name: **Single/multiple** component metallic bone fixation appliances
and accessories
Regulatory Class: II
Product Code: JDS
Dated: April 01, 2005
Received: April 14, 2005

Dear Ms. Jordan:

This letter corrects our substantially equivalent letter dated May 04, 2005 regarding the incorrect Regulation Number and Regulation Name. The May 04, 2005 letter listed 888.3020 as the Regulation Number and Intramedullary Rod as the Regulation Name.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam Provost", is written over the typed name.

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

prescription Use X
(Per21 CFR 801.109)

OR

Over-the-counter Use _____
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K050938

1050938

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MAY - 4 2005

510(K) SUMMARY**KNEE FUSION NAIL**

SUBMITTER'S NAME: Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS: 1450 Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER: 901-399-5042
CONTACT PERSON: Laurie Jordan
DATE SUMMARY PREPARED: April 1, 2005
TRADE OR PROPRIETARY DEVICE NAME: Knee Fusion Nail
COMMON OR USUAL NAME: Intramedullary Nail
DEVICE CLASSIFICATION: 21 CFR 888.3020, Intramedullary Fixation Rod
DEVICE CLASS: Class II
PANEL CODE: Orthopedic/87

DEVICE INFORMATION:**INTENDED USE:**

Knee Fusion Nails are for intramedullary knee arthrodesis.

DEVICE DESCRIPTION:

A Knee Fusion Nail is inserted into the medullary canal of long bones for knee arthrodesis. The design of the Knee Fusion Nail is based on Smith & Nephew's (formally Richards Medical) experience with intramedullary nail systems, which dates back to the 1950's. The Knee Fusion Nail includes intramedullary interlocking nails with corresponding screws. The Knee Fusion Nail and corresponding screws are made of Ti-6Al-4V titanium alloy with holes/slots for optional locking screws on both ends of the nail. Locking screws are available for optional proximal and distal locking. Screws are available in 5.0mm, and 6.4mm diameters with varying lengths. The screws were previously cleared in 510(k) K981529. The device is intended for single use.

MECHANICAL AND CLINICAL DATA

A review of the four point bend fatigue test indicated that the Knee Fusion Nail is equivalent to devices currently used clinically.

SUBSTANTIAL EQUIVALENCE INFORMATION:

The substantial equivalence of the Knee Fusion Nail is based on its similarities in indications for use, design features, and operational principles to the Russell-Taylor Intramedullary Knee Fusion Nail (K893377 and K983942). Both of these devices are inserted into the medullary canal of long bones for knee arthrodesis. Each one of these devices has holes/slots for optional locking screws on the proximal and distal ends. The difference between the Knee Fusion Nail and these predicate devices are that the predicate devices are made of ASTM F 138 and ISO 5832/1 stainless steel and the Knee Fusion Nail is made of Ti-6Al-4V Titanium Alloy. The differences between the Knee Fusion Nail and these predicate devices do not affect safety and effectiveness.